Cost Effectiveness and Efficiency of Reusing Single-use Medical Devices

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ABSTRACT

Background: *Reusing single-use medical devices is a very important and complicated process since the implementation requires both operational and technical skills, even for professional users. The aim of our study was to determine the cost effectiveness and efficiency of reusing single-use medical devices.*

Method: *The study was a cross-sectional study conducted between July and December 2013. It compared two groups of patients who underwent endoscopic retrograde cholangiopancreatography (ERCP) examination at the Digestive Endoscopy Center, Cipto Mangunkusumo Hospital, Jakarta. Patients in the first group received new single-use medical devices; while patients in the other group received the re-used single-use medical devices. Reprocessing for reusing single-used medical devices was conducted according to standard procedures of decontamination and sterilization.*

Results: *Reusing medical devices were more commonly found (50.9%) in ERCP procedures than using new medical devices (49.1%). There was no significant difference on operator satisfaction between using the re-used and new medical devices (p = 0.062). There was lower average cost for reusing medical devices than using new medical devices (IDR 198,818,250.00 vs. IDR 594,354,000.00; p = 0.000); percentage of success rate for reusing was lower than new medical devices (80% vs. 90,6%; p = 0.203). There was also no significant difference regarding the negative impacts such as fever or infection of reusing medical devices compared to using new medical devices (p = 0.676).*

Conclusion: *This study has shown good effectiveness in terms of operator satisfaction, success rate and impacts on patients. The cost for reusing medical devices is more efficient than using new medical devices.*

Keywords: *effectiveness, efficiency, reusing medical devices, new, endoscopy*

ABSTRAK

Latar belakang: *Penggunaan alat medis sekali pakai (single-use) yang dipakai kembali (re-use) menjadi sangat penting dan kompleks dalam menerapkan kemampuan operasional dan teknik pada profesional pengguna alat tersebut. Tujuan penelitian ini adalah untuk menilai efektifitas biaya dan efisiensi penggunaan perangkat medis single-use yang dijadikan re-use.*

Metode: *Penelitian ini merupakan penelitian potong lintang dilakukan pada Juli hingga Desember 2013. Penelitian membandingkan dua kelompok pasien yang menjalani pemeriksaan endoscopic retrograde cholangiopancreatography (ERCP) di Pusat Endoskopi Saluran Cerna (PESC), Rumah Sakit Cipto Mangunkusumo, Jakarta. Pasien pada kelompok pertama menerima tindakan dengan alat medis baru; sedangkan pasien di grup lainnya menerima tindakan dengan alat medis re-use. Proses penggunaan alat medis re-use dilakukan sesuai dengan prosedur dekontaminasi dan sterilisasi yang berlaku.*

Hasil: *Penggunaan alat medis dalam tindakan ERCP lebih banyak menggunakan alat re-use (50,9%) di bandingkan alat baru (49,1%); kepuasan operator pada alat re-use maupun alat baru tidak berbeda secara signifikan (p = 0,062); rata-rata biaya pada penggunaan alat re-use lebih rendah dibandingkan pada alat baru*

(Rp 198.818.250,00 vs. Rp 594.354.000,00; p = 0.000); persentase keberhasilan penggunaan alat re-use lebih rendah dibandingkan pada alat baru (80% vs. 90,6%; p = 0,203); dampak berupa terjadi demam atau infeksi pada penggunaan alat re-use dan alat baru tidak menunjukkan perbedaan yang signifikan (p = 0,676).

***Simpulan:** Penggunaan alat re-use menunjukkan efektifitas yang baik pada kepuasan operator, keberhasilan alat, dan dampak pada pasien. Biaya penggunaan alat re-use lebih efisien dibanding dengan penggunaan alat baru.*

***Kata kunci:** efektifitas, efisiensi, perangkat medis re-use, baru, endoskopi*

INTRODUCTION

Reprocessing single-use medical devices using the applied principles of sterilization is essential to reduce medical device waste caused by the use of disposable or single-use medical devices. In addition, reusing single-use medical devices can save costs in hospitals.[1] One of reusing procedures for single-use devices that can be applied at a Digestive Endoscopy Center is reusing biopsy forceps and other accessories for endoscopic retrograde cholangiopancreatography (ERCP) procedures.

There is an increasing number of ERCP procedures at the Digestive Endoscopy Center; therefore, it demands for better quality service but at affordable price, which becomes a great challenge challenge for this unit. Reaching better quality service may include providing reliable medical peripheral devices used for the procedures as well providing guarantee for safety.

Reusing critical and semi-critical medical devices has been carried out by the Digestive Endoscopy Center. Reusing medical devices is an effort to reduce cost and maximize the effectiveness of utilizing certain disposable or single-use medical devices.[2,3] The aim of our study was to determine the cost effectiveness and efficiency of reusing single-use medical devices to provide better quality service with affordable in medical institutions.

METHOD

The study was a cross-sectional study conducted between July and November 2013. It compared two groups of patients who underwent ERCP examination at the Digestive Endoscopy Center, Cipto Mangunkusumo Hospital, Jakarta. Patients in the first group received new single-use medical devices; while patients in the other group received the re-used single-use medical devices. Reprocessing for reusing single-used medical devices was conducted according to standard procedures of decontamination and sterilization.

The design of this study is an analytical survey using questionnaire and direct interviews as tools for collecting and measuring data. The study population was patients who visited the Digestive Endoscopy Center with the following sample calculation:

$$n = \frac{\left\{Z_{1-\alpha/2}\sqrt{(2P(1-P))} + Z_{1-\beta}\sqrt{(P1(1-P1)) + P2(1-P2)}\right\}^2}{(P1-P2)^2}$$

P1 = The proportion of success on the cost efficiency of the group receiving new single-use medical devices (2.58%)
P2 = The proportion of success on the cost efficiency of the group receiving re-used medical devices
α = 0.05
Zα = 1.96
ß = 0.20

Based on the formula, the minimum sample size were 90 subjects and to anticipate drop out, additional 20% sample size was calculated; therefore, the total number of samples were 108 subjects.

RESULTS

Data of ERCP procedures conducted at the Digestive Endoscopy Center was collected for 5 months and approximately, 21 samples were obtained monthly. The results of our study are presented in the following figures.

The Use of Accessories

The use of accessories devices can be observed including the type of accessories devices used in patients who underwent the ERCP procedures.

Out of 108 samples, there were 53 (49.1%) patients receiving new single-use medical accessoriesdevices and there were 55 (50.9%) patients who received re-used medical accessories devices during ERCP. Therefore, re-used medical devices was more common than the new single-use devices.

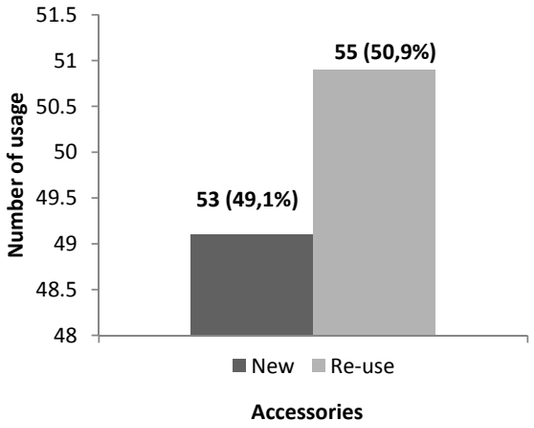

Figure 1. The use of accessories devices at Digestive Endoscopy Center in 2013

Operator Satisfaction

The satisfaction level of operators using new single-use and re-used medical devices was measured by a subjective assessment with a score ranged between 1 and 10. Greater satisfaction was showed by higher score. The results can be seen in the following figure.

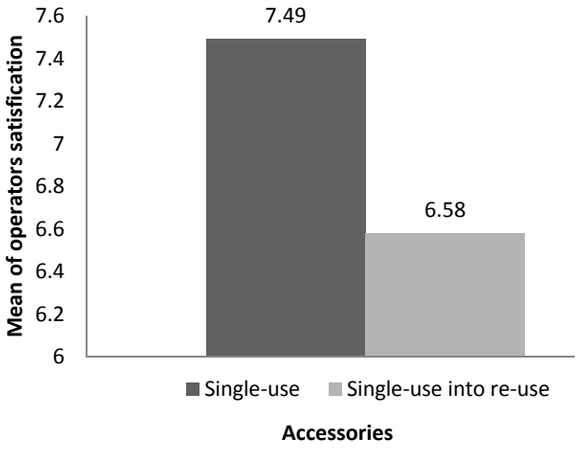

Figure 2. Average operator satisfaction on the use of accessories devices at Digestive Endoscopy Center in 2013

We found that the average operator satisfaction on the performance of single-use accessoriesdevices was 7.49 ± 2.181; while for re-used accessories devices, the operator satisfaction was 6.58 ± 2.793. Statistical analysis was performed to evaluate operator satisfaction between using new single-use medical devices and using re-used medical devices. The analysis was carried out using independent t-test and we found $p = 0.062$ ($p > 0.05$), which indicated that there was no significant correlation of operator satisfaction between using new single-use and re-used medical devices.

Cost Efficiency

Cost efficiency was measured by calculating the costs incurred for using the accessories medical devices. The cost of new single-use accessories devices was calculated based on the price of each type of devices listed in the price list at the Pharmacy Unit of Cipto Mangunkusumo Hospital; while the cost for re-used accessories medical devices was calculated based on the cost of sterilization for each accessorydevices according to the price list at the Sterilization Center of Cipto Mangunkusumo Hospital. The data of cost efficiency are shown in Figure 3 below.

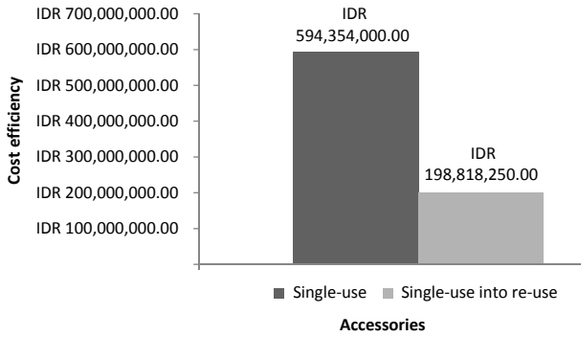

Figure 3. Average cost of efficiency on the use of accessories devices at Digestive Endoscopy Center in 2013

The data showed that the average cost for usage of using new single-use medical device was IDR 2,377,416.00 ± IDR 1,462,166,225.00 and the cost for reusing the device was IDR 795,273.00 ± IDR 343,919, 966.00.

Cost efficiency was evaluated by comparing the costs incurred for 250 patients of ERCP in year 2013 between those receiving new single-use and re-used medical devices. For new single-use devices, the costwas IDR 594,354,000.00; while for re-used devices, the cost was IDR 198,818,250.00. Statistical analysis which compared the total cost revealed $p = 0.000$ ($p < 0.05$), which indicated that there was a significant correlation on the average cost between those receiving new single-use and re-used medical devices.

The Rate of Successful ERCP Procedure

The rate of successful ERCP procedure could be determined by evaluating successful cannulation using new and re-used single-use medical devices. The data are presented in Figure 4.

Our data showed that out of 53 procedures using new single-use medical devices, there were 48 procedures with successful cannulation (90.6% success rate); while out of 55 procedures using re-used medical

devices, there were 44 procedures with successful cannulation (80% success rate).

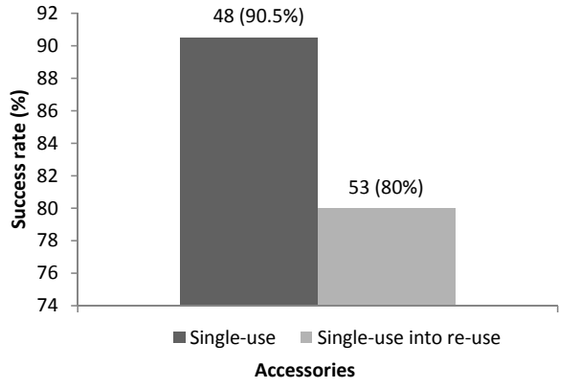

Figure 4. The rate of successful ERCP procedure on the use of accessories devices at Digestive Endoscopy Center in 2013

Statistical analysis was performed to observe the correlation between the utilization of single-use medical devices and re-used single-use medical devices using Chi-square continuity correction test. Our study results revealed $p = 0.203$ ($p > 0.05$), which indicated that there was no significant different correlation.

Impacts of Using the Accessories Medical Devices

All patients who used new single-use and re-used accessories medical devices were monitored for 48 hours after being evaluated whether they had a fever higher than 37.5˚C or not.

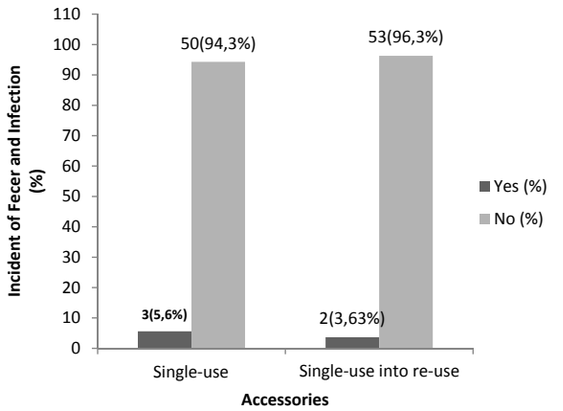

Figure 5. The incidence of fever and infection caused by the utilization of accessories medical device at Digestive Endoscopy Center in 2013

Our data showed that there were 5 (4.62%) subjects who had fever; while 103 (95.37) subjects had no fever during the 48-hour of follow up after the ERCP procedure.

Statistical analysis was performed to evaluate the correlation between the incidence of fever and the utilization of accessories medical devices using Chi-square and Fisher exact test. The results revealed $p = 0.676$ ($p > 0.05$), which indicated that there was no correlation between the incidence of fever and the utilization of medical devices, either using the new single-use or re-used devices.

DISCUSSION

Many health institutions including hospitals and medical equipment companies have started processing the single-use medical devices into re-used devices. Our study revealed that out of 108 procedures using medical devices, 53 procedures utilized the new single-use devices and 55 (50.9%) procedures utilized the re-used device. Before the regulation on reusing single-use medical devices has been established, the utilization of re-used medical devices has caused many casualties such as disease transmission due to inappropriate standard instrument handling. Therefore, Food and Drug Administration (FDA) has issued the regulations in 2000 regarding reusing single-use medical devices, particularly on the issue of sterilization.[4]

The satisfaction level of operators was rated by an assessment on the operators' performance when using the accessories medical devices and was presented in a score ranged between 1 and 10. Higher score showed greater satisfaction. The results can be seen in the following figure. The results of our study showed that the average operator satisfaction when using the re-used single-use medical devices was lower than when they used the new one. For using the re-used medical devices, the average satisfaction was 7.41; while for using new single-use medical devices, the satisfaction was 7.91. Therefore, it suggests that the operator performance using new single-use medical devices was more satisfying than using re-used medical devices although there was a low difference on average satisfaction.

Our findings on cost efficiency showed that the cost for using new single-use medical device in 2013 was as much as IDR 594,354,000.00; while the cost of reusing the medical device was IDR 198,818,250.00. Statistical analysis was performed to observe the correlation on the total cost between both condition and revealed that $p = 0.000$ ($p < 0.05$), which can be interpreted that there was a significant difference of average cost between utilization of new single-use device and re-used medical device. In terms of the cost, utilization of re-used medical devices is more efficient than using the new single-use device; moreover, our study result did not show much difference on the average operator satisfaction between the utilization

of re-used and the new single-use medical devices. Therefore, it can be concluded that the utilization of re-used medical devices is more efficient than using new single-use devices. A French study, which used retrospective analysis on minimum cost of reusing forceps instruments, showed that the cost of reusing forceps instruments for 90 times is about USD 364 with an average cost of USD 6.84 per instrument, which is cheaper than using new single-use medical device with the cost between USD 10.70 and USD 15.60.[7,10]

Reusing single-use medical devices has been carried out in many situation since it has been demonstrated to be morecost effectivecompared tothe use of new single-use medical devices.[7] Many studies have been conducted to compare the utilization of re-used medical devices and using new single-use medical devices, particularly about the cost and performance.[11] One of those studies is the study about reusable biopsy forceps. The study showed that using reusable biopsy forceps is cheaper than using the new instrument since the reusable forceps were used repeatedly. The forceps were used between 20 and 91 times without repair and more than 315 times with repair.[7,8,9,11]

The success rate of treatment was observed based on how many medical devices had been used and replaced due to malfunction or damage. Our study showed that there were 53 procedures using new single-use medical devices and 5 devices were broken and replaced; while there were 55 procedures using re-used medical devices and 11 devices were broken and replaced. The percentage of success rate was 90.5% fornew single-use device and 80% for the utilization of re-used device. It can be concluded that there was lower percentage of reusing than using new single-use medical devices.

Regarding the impacts of reusing medical devices, our study found 2 cases of fever higher than 37.5˚C and infection adjacent to the surgical area (3.63%); while for the utilization of new single-use medical devices, there were 3 cases of fever with initial dissolved oxygen (IDO) of 5.6%. Moreover, no fever was found in other cases that utilized re-used medical devices (96.36%) compared to the utilization of new single-use medical devices (94.3%). Therefore, it can be concluded that the trend was there was less impacts of utilizing re-used medical device than the utilization of new single-use device, even though the statistic result showed no significant difference.

In addition, single-use devices can be re-used under special circumstances; however, it should be noted that there are some risks related to reusing the single-use medical devices. There is an increased risk of infection and the operator's performance of utilizing the devices may be inadequate or unsatisfactory after reprocessing. Policies on reprocessing or reusing medical device should include identification of: 1) Devices and materials that could never be re-used; 2)The maximum number ofre-use processfor certain devices and materials; 3) Type of use and damages, including others that indicate medical devices cannot bere-used; 4) The cleaning process for the devices must be done immediately after being used and must follow clear protocols; 5) The process of collection, analysis and use of data related to infection control for reusing devices and materials.[5]

Based on the results of our study, we suggest further studies for similar issue including defining the correlation between the utilization of new single-use and re-used medical devices as well as other comprehensive medical aspects, particularly on the impact of such utilization on the patients. The medical aspects should not only limited to the incidence of fever and infection at the surgical area, but also for other medical aspects and to determine whether the impacts are caused by the utilization of medical devices or not since our study did not focus on the comprehensive medical aspects.

CONCLUSION

Reusing single-use medical devices at the Digestive Endoscopy Center has shown good effectiveness in terms of operator satisfaction, success rate and impacts on patients, which showed significant differences. The cost for reusing medical devices is more efficient than using new medical devices. We conclude that reusing the single-use medical device is more effective and efficient than using new medical devices.

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